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April 25, 2005

Food and Drug Administration
Center for Devices and Radiological Health
Regulations Staff (HFZ-215)
1350 Piccard Dr.
Rockville, MD 20857

RE: PMA P820075 Lamicel® Osmotic Cervical Dilator; Petition for Reclassification Under Section 513(e)

To Whom It May Concern:

Medtronic Xomed submits this summary and citation to provide information to the FDA for a reclassification determination of the device known as Lamicel® Osmotic Cervical Dilator, as described by product code LOB.

This submission is being submitted under section 513(e)(2) of the Food Drug and Cosmetic Act to support FDA consideration for the reclassification of the device "Lamicel® Osmotic Cervical Dilator" from Class III to Class II.

1. Identification, Specific Description of Types of Device, and Intended Use:

Hydroscopic cervical dilators are described in Regulation 884.4260 as "a device designed to dilate (stretch open) the cervical os by cervical insertion of a conical and expansible material made from the root of a seaweed (Laminaria digitata or Laminaria japonica). The device is used to induce abortion."

The underlined portion of the description highlights the difference between the class III Lamicel® Osmotic Cervical Dilator and the class II hydroscopic laminaria cervical dilator. The synthetic material of Lamicel® was designed to mimic the effect of the naturally occurring laminaria. The synthetic material does not increase any known risk to health in the use as a cervical dilator, and only limited special contols are required for assuring safety and efficacy.

Information About Lamicel® Osmotic Cervical Dilator:

Description and Use: Lamicel® Osmotic Cervical Dilator (hereinafter referred to as Lamicel®) has been marketed since 1983 as a class III device. Currently the only other product marketed under the same product code is Dilapan-S, a synthetic cervical dilator registered by JCEC Co.

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Lamicel® is a sterile, disposable device which ripens and/or dilates the cervix uteri. The device is composed of a synthetic, white polyvinyl alcohol foam sponge, impregnated with 300 to 500mg of magnesium sulfate. Lamicel® is introduced into the cervical canal and left in place for up to twenty-four (24) hours. Fluid is transferred from the cervical tissue, into a synthetic sponge, which retains the fluid. As the fluid is withdrawn, a gradual dilation of the cervix occurs. The sponge is currently listed with the FDA for use as surgical sponges, nasal tampons, eye wicks, ear drains, and other surgical devices. This material has been extensively tested and has passed USP requirements for toxicity and pyrogens.

The Lamicel® product insert, package labeling, and process flow map are supplied in **Appendix A.**

2. Specific Risks to Health Posed by the Device:

A literature review article published in 2004[1] found no reports of safety complications attributed to Lamicel®. The same review reported Dilapan fragmenting in 22 of 506 cases all of which were benign outcomes. It must be noted that this study took place with the original Dilapan device which was withdrawn from the market in 1995 and reintroduced in 2002 as the modified Dilapan-S. A 1989 review article by N. Johnson summarized the problems with laminaria as including fatal sepsis, mitigation of the tent into the cavity, tent expulsion, tent fracture and fragmentation occurring during removal, leaving pieces of seaweed within the canal and uterine cavity, and disintegration of entire batches of laminaria[2]. Laminaria is a Class II device under 21 CFR 884.4260.

3. Benefits Associated with the Device:

Although laminaria dilation is generally regarded as safe and effective, it still harbors risks and may be associated with side affects. During clinical trials submitted with the original PMA, it was found that unlike laminaria, Lamicel® is incapable of exerting high mechanical pressure on the human cervix. Also, a study published by Lichtenburg reports that synthetic devices have the following potential advantages over laminaria "1) assured sterility, 2) consistency of length and shape, and theoretically, 3) greater predictability of effect." Unlike synthetic devices, laminaria has been found to retain potential genital pathogens even after gas sterilization since seaweed contains spores that are resistant to the sterilization process[3].

Synthetic dilators have reported a reduced time to effectiveness. Compared to Laminaria which does not achieve its full potential clinical effect until 24 hours, Lamicel® achieves maximum clinical effect within 4 hours and Dilapan within 2-4 hours during the first trimester of pregnancy[1]. Also, physicians typically use multiple laminaria per cervical treatment where there are no reported instances where more than one Lamicel® was required per cervical treatment.

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[1] Lichtenberg, S.; Complication of Osmotic Dilators, Obstetrical and Gynecological Survey, 2004 Jul;59(7);528-536

[2] Johnson, N.; Review. Experiences with Lamicel. Journal of Obstetrics and Gynaecology 1989; 9(4).

[3] Wells EC, Hulka JF.; Cervical dilation: a comparison of Lamicel and Dilapan. Am J Obstet Gynecol. 1989 Nov;161(5):1124-6

4. Recommendation:

Medtronic Xomed recommends to the FDA that Product Code LOB (Dilator, Cervical, Synthetic Osmotic) be down classed from Class III to Class II.

5. Summary of Reasons for Recommendation:

Medtronic Xomed provides herein a literature review of published articles which have become available since the approval of Lamicel®. The literature review supports the substantial equivalence of Synthetic Osmotic Cervical Dilators to Hygroscopic Laminaria Cervical Dilators. The synthetic material does not increase any known risk to health in use as a cervical dilator, and only limited controls are required for assuring safety and efficacy. The literature publications provided show a low complication rate and a risk frequency equivalent to or less than that of laminaria due to increased the increased sterility of the synthetic material. The benefits gained from eliminated risk of infection, due to seaweed spores able to withstand the sterilization process, and increased predictability come with no new risks to health when compared to natural material.

The necessary controls can be afforded in the Class II classification. Any subsequently marketed synthetic cervical dilator, when compared to the Medtronic Xomed device, could be found as equivalent under the process of 510(k) premarket notification.

6. Adverse Events Experience with the Device:

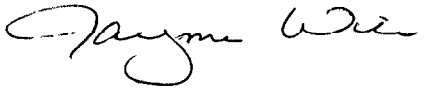
A review of the product compliant records and Medical Device Reports file of Medtronic Xomed for the 16 years that Lamicel® has been on the market was completed and no adverse event (MRD's) have been reported. This lack of serious adverse events is supportive of the limited risk to health that is associated with synthetic cervical dilators manufactured under specific controls.

7. Summary and Bibliography of Published Literature:

Provided in **Appendix B** is a Literature Review of published articles on Lamicel® along with all readily available published articles.

This petition is being submitted in triplicate. If you have any questions regarding this submission, please contact me directly at (904) 279-7586, or by email at jayme.wilson@medtronic.com, or contact Dave Timlin at (904) 296-7532.

Sincerely,



Jayme Wilson
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